Litigating to Address the Psychiatric Drugging of Poor Children

International Society for Ethical Psychology and Psychiatry (ISEPP)

Individuals Matter: Building a Better Science for Psychology and Psychiatry

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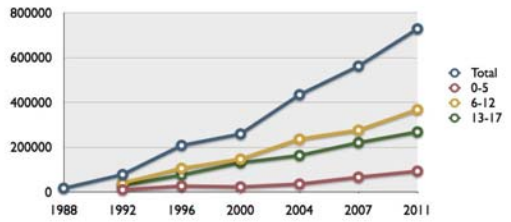
Law Project for Psychiatric Rights
(PsychRights)

- Public Interest Law Firm
- Mission: Mount Strategic Litigation Campaign Against Forced Psychiatric Drugging and Electroshock.
- Drugging of Children & Youth a Priority

Psychiatric Drugging of Children

- 1 in 10 boys on stimulants
- More than 1% of youth under 18 Given Neuroleptics
- No long term benefit; short term benefit mainly for adults
- 1 in 40 on antidepressants
  - Prozac Boys Study: 23% developed manic like symptoms; 19% more drug induced hostility
  - Pediatric Bipolar Rate soars
    - From close to none in 1995 to 800,000 by 2003
    - Then come the neuroleptics & anticonvulsants misbranded as mood stabilizers.
- Many Now on Neuroleptics, even six month olds.
- Great physical harm
- Child MH Disability Rate Soars from Essentially Zero in 1987 to 800,000 by 2011.

Children on SSI Disability Due to Mental Illness in the Prozac Era



Prior to 1992, the government's SSI reports did not break down recipients into subgroups by age. Source: Social Security Administration reports, 1988-2007.

Three Legal Approaches

- Civil Rights Violations Under 42 U.S.C. §1983
- Off-Label Prescribing Constituting Medicaid Fraud
- FDA Petitions to Withdraw Pediatric Drug Approvals

Civil Rights Violations Under 42 U.S.C. §1983

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable.

Most Drugging of Children & Youth in State Custody Unconstitutional

- State obligated to protect children & youth in custody from harm.

Deshaney v. Winnebago County, 489 U.S. 189, 109 S.Ct. 998 (1989):

> "[W]hen the State by the affirmative exercise of its power so restrains an individual's liberty that it renders him unable to care for himself, and at the same time fails to provide for his basic human needs-e.g., food, clothing, shelter, medical care, and reasonable safety-it transgresses the substantive limits on state action set by the Eighth Amendment and the Due Process Clause."

M.D. v. Abbott

152 F.Supp.3d 684 (SD Tex. 2015)

- State custody of a child creates a "special relationship" that triggers substantive due process protections.
- Foster children have a Fourteenth Amendment substantive due process right to be free from an unreasonable risk of harm caused by the State.
- State has duty to keep foster children free from an unreasonable risk of harm.
  - Don't have to wait for harm to occur
- Includes psychological as well as physical harm.

Payment of Off-Label Prescriptions Restricted Under Medicaid

- Medicaid reimbursement prohibited for outpatient drug prescriptions except for "medically accepted indications," which means indications approved by the Food and Drug Administration (FDA) or supported in at least one of the following compendia:
  - American Hospital Formulary Service Drug Information,
  - United States Pharmacopeia-Drug Information (or its successor publications), or
  - DRUGDEX Information System.

DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation

Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Key:	White Background: Medically Accepted Indication			
	Orange Background: Pediatric Indication cited, but not supported by DRUGDEX			
	Red Background: No Pediatric FDA Approval or DRUGDEX citation			
Abilify (Aripiprazole) - Antipsychotic				
	Autistic disorder-Psychomotor agitation	Yes (6-17)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug		
	Narcolepsy	Yes (for 6 years old and up (immediate release only)		
Ambien (zolpidem) - nonbenzodiazepine Hypnotic				
	Insomnia, Short-term treatment	No		Class III
Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
	Depression	No		Class IIb

False Claims Act

(31 U.S.C §3729, et seq.)

- Civil War Era Statute to Address Rampant Fraud Against Government
- Amended in 1986, 2009 and 2010
- Allows citizens to bring suit on behalf of the government and share in recovery if any.
- Called "Relators" (for the King)

False Claims

- It is a False Claim to:
  - **(A)** knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval

(to the Federal Government)

31 USC §3729(a)(1)

Knowingly Defined As:

i. Actual knowledge;
ii. Deliberate ignorance of the truth or falsity; or
iii. Reckless disregard of the truth or falsity

No proof of intent to defraud required

31 USC §3729(b)(1)(a)

Penalties

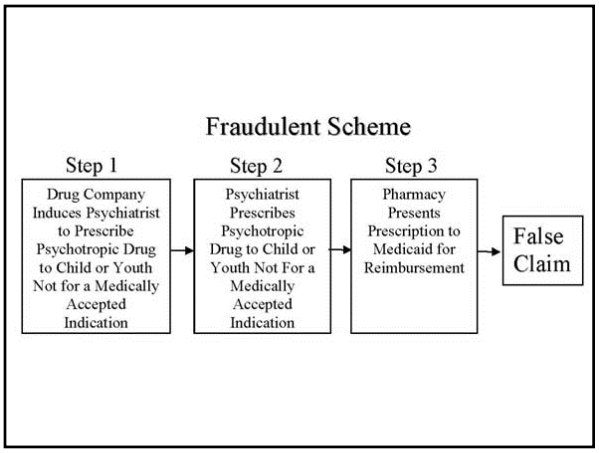
- $5,500 to $11,000 per false claim, plus treble damages.
  - Each offending prescription is a false claim

31 USC §3729(a)

Relator Recovery

- If Government intervenes and takes over case, Relator receives 15% to 25%.
- If Government doesn't intervene, Relator receives 25% to 30%.

31 USC §3730(d)



$Billion Settlements Against Drug Companies Not Effective

- Cost of doing business.
- Have established practice by psychiatrists and other prescribers
- The Government is continuing to pay the false claims

Procedural Hurdles

- Public Disclosure Bar
- Particularity
- First to File
- Attorney Required
- Six year statute of limitations

Public Disclosure Bar
(As Amended in 2010)

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 USC §3730(e)(4)(A)

Model Complaint

- Drafted for former foster youth, but anyone with non-public information (i.e., specific prescriptions) can bring.
  - Used in *ex rel. Watson v. King-Vassel*

A Tale of Two Cases

PsychRights v. Matsutani (9th Cir.)	*Watson v. King-Vassel* 7th Cir
• 30+ Defendants • Ignored Susan Stefan's Excellent Advice Not to Name So many • 9th Circuit in non-precedential Disposition: The government knows all about the fraud and doesn't care so why should we? (Public Disclosure Bar)	• Psychiatrists Cause False Claims When Prescribing Off-Label to Medicaid Patient not supported by Any Compendia • Won in trial court on Public Disclosure Bar • On Remand, trial court threatened *relator* into folding • Terrific Precedent, Though

Questions (to be litigated)

- What does "support" in a compendia mean?
  - Drugdex Codes
    - Can a positive report of "3 mentally deficient children & adolescents" receiving Depakote generating a IIb rating constitute "support?"
  - Is almost all polypharmacy a violation?
- Can Prescribers, Employers & Pharmacies be charged with knowledge?
  - *Heckler* (Supreme Ct) held charged with knowledge of program requirements
  - 7th Cir.

FDA Drug Approval Criteria

- Drugs are required to be safe & effective for approval. 21 U.S.C. § 355(b)(1)
- Withdrawal of Approval under 21 U.S.C. § 355(e) if:
  - Post approval data show that the drug is unsafe for approved uses
  - New evidence shows lack of substantial evidence drug will have the effect it purports to have under the approved application
  - The application contains any untrue statement of a material fact

Citizen Petitions

- An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. 21 CFR 10.25(a)
- Citizens' Petition procedures. 21 CFR 10.30.
- Assume Adverse FDA Decision And Need to Appeal to Federal Court